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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/194,552 03/23/99 BROOKS

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EXAMINER

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ART UNIT	PAPER NUMBER
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1642

242

DATE MAILED:

12/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 09/194,552	Applicant(s) Brooks et al.
Examiner Alana M. Harris, Ph. D.	Group Art Unit 1642



Responsive to communication(s) filed on September 11, 2000.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

Claim(s) 49-84 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 49-53, 55, 56, 58-62, 64, 67-72, and 74-84 is/are rejected.

Claim(s) 54, 57, 63, 65, 66, and 73 is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been  
 received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_.  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1642

**DETAILED ACTION**

1. Claims 49-84 are pending.

Claims 1-48 have been canceled.

Claims 49-84 are examined on the merits.

***Election/Restriction***

2. Applicant's election without traverse of Group I (newly added claims 49-84 which correspond to canceled claims 1-25 and 44-48) in Paper No.14 is acknowledged.

***Priority***

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e), as well as 35 U.S.C. 119 (a)-(d) is acknowledged. However, the provisional application, 60/018,773, filed May 31, 1996 upon which priority is claimed fails to provide adequate support of SEQ ID NO 7, 9 and 11-22 under 35 U.S.C. 112 for claims 49-84 of this application. Provisional application 60/015,869, filed May 31, 1996 was not available for the Examiner's review. Applicant is invited to provide a copy of the specified provisional application. The priority date granted to the instant application is May 30, 1997, the filing date of PCT/US97/09099.

Art Unit: 1642

*Specification*

4. This instant application, filed under former 37 CFR 1.60 lacks the necessary reference to prior applications. A statement reading "This application claims priority to International Application PCT/US97/09099, filed May 30, 1997, Provisional Application #60/018,773, filed May 31, 1996 and Provisional Application #60/015,869, filed May 31, 1996" should be entered following the title of the invention or as the first sentence of the specification. Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority under 35 U.S.C. 119(a)-(d), a claim for such foreign priority must be made in this application.

5. The disclosure is objected to because of the following informalities: the brief description of the figures lack a separate brief description: Figures 7A-7E, Figure 15C and Figure 15D. Correction is required.

6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Art Unit: 1642

174100  
and  
66 *Claim Objections*

7. Claims 54, 57, 63, 65 and 73 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Claim Rejections - 35 U.S.C. § 112*

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 50, 55, 61 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 50 and 61 are vague and indefinite in the recitation "organic mimetic compounds". What is an organic mimetic compound? What organic materials are encompassed by these minute peptides?

b. The recitation "said organic mimetic" in claims 55 and 64 lacks proper antecedent bases in claim 49 and 60, respectively. Appropriate correction is required.

Art Unit: 1642

***Claim Rejections - 35 U.S.C. § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 56 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Collier et al. (J. Biol. Chem 263(14):6579-6587, 1998). Collier discloses a polypeptide that includes an amino acid residue sequence shown in SEQ ID NO:11, 12, 13, 14 and 16 of the instant invention (see see attached database sheet, Accession A28153).

12. Claims 56 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (J. Biol. Chem 266(8):5113-5121, 1991). Chen discloses a polypeptide that includes an amino acid residue sequence shown in SEQ ID NO:18, 19, 20, 21 and 22 of the instant invention (see attached database sheet, Accession Number Q90611).

13. Claims 60, 62, 71, 72 and 82-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Friedlander et al. (Science 270:1500-1502, December 1, 1995). Friedlander discloses a method for inhibiting angiogenesis in a tissue, a solid tumor or carcinoma comprising administering to said tissue a composition comprising an angiogenesis-inhibiting amount of  $\alpha_{\text{v}} \beta_5$ ,

Art Unit: 1642

see page 1500, column 3, first full paragraph (claims 60, 71 and 72). The method for inhibiting angiogenesis teaches an integrin  $\alpha_{\text{v}} \beta_5$  antagonist that inherently, preferentially inhibits fibrinogen binding to  $\alpha_{\text{v}} \beta_5$  compared to fibrinogen binding to  $\alpha_{\text{IIb}} \beta_3$  (claim 62), the same as that claimed.

Additionally, Friedlander discloses the claimed method wherein said angiogenesis is induced by a vascular endothelial growth factor cytokine and said angiogenesis is corneal angiogenesis (claims 82-84).

***Claim Rejections - 35 U.S.C. § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 49 and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedlander et al. (Science 270:1500-1502, December 1, 1995). Friedlander teaches pharmaceutical agent that is effective for inhibiting angiogenesis in a tissue that can be used for treating conditions by inhibition of angiogenesis and wherein said pharmaceutical agent comprises an angiogenesis-inhibiting amount of an  $\alpha_{\text{v}} \beta_5$ , see whole document (claim 49). This article of manufacture is effective for inhibiting angiogenesis in a tissue that is:

Art Unit: 1642

(a) inflamed and said condition is arthritis or rheumatoid arthritis;  
(b) a solid tumor or solid tumor metastasis;  
(c) as well as the said tissue is retinal tissue and said condition is retinopathy, diabetic retinopathy or macular degeneration, see page 1501, column 3 (claims 51-53).

Friedlander does not teach an article of manufacture comprising packaging material and a pharmaceutical agent contained within said packaging material. However, although the claims recite packaging material, no positive recitation of the packaging ingredients/elements distinguishes the claim over the reference. Therefore, the reference reads on the claimed packaging materials. Further, it would have been *prima facie* obvious and it is a well-known convention in the art to place the recited elements in a packaging form for the advantages of convenience and economy. Thus, the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

16. Claims 49, 50 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collier et al. (J. Biol. Chem 263(14):6579-6587, 1998) and Chen et al. (J. Biol. Chem 266(8):5113-5121, 1991). The teachings of Collier and Chen have been discussed above.

Collier and Chen do not teach an article of manufacture comprising packaging material and a pharmaceutical agent contained within said packaging material. However, although the claims recite packaging material, no positive recitation of the packaging ingredients/elements distinguishes the claim over the reference. Therefore, the reference reads on the claimed

Art Unit: 1642

packaging materials. Further, it would have been *prima facie* obvious and it is a well-known convention in the art to place the recited elements in a packaging form for the advantages of convenience and economy. Thus, the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

17. Claims 67-70, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedlander et al. (Science 270:1500-1502, December 1, 1995). Friedlander teaches the claimed method as discussed above. However, Friedlander does not teach the method wherein said tissue is arthritic and present in a mammal with rheumatoid arthritis and the said tissue is retinal tissue or eye disease tissue and said angiogenesis is retinal angiogenesis in a patient with diabetic retinopathy or macular degeneration. Friedlander's method neither teaches that the method used in the treatment of an eye disease selected from diabetic retinopathy, age-related macular degeneration, presumed ocular histoplasmosis, retinopathy or prematurity and neovascular glaucoma and wherein said angiogenesis is present in a patient having a corneal neovascular disorder consisting of corneal transplantation, herpetic keratitis, luetic keratitis, pterygium and neovascular pannus associated with contact lens use.

Notwithstanding, Friedlander results (see page 1501, column 3) suggests that the recited methodology could be effective in treating an array of pathologic processes, including blindness and inflammatory disease. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer an angiogenesis-inhibiting amount of

Art Unit: 1642

an  $\alpha_{\text{m}} \beta_5$  antagonist to a subject with an inflammatory disease such as arthritis and blindness-associated diseases, such as luetic keratitis, macular degeneration and a host of other corneal neovascular disorders. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings of Friedlander that angiogenesis is associated with a multitude of pathologic processes and an inhibitor of this critical unrestrained biologic process could limit the growth of new blood vessels.

18. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Friedlander et al. (Science 270:1500-1502, December 1, 1995), in view of U.S. Patent Number 5,567,693 (October 22, 1996). Friedlander teaches a method for inhibiting angiogenesis as discussed above. Friedlander does not teach the method wherein said administering is conducted in conjunction with chemotherapy.

However, U.S. Patent # 5,567,693 teaches the administration of chemotherapeutic agents in combination with an inhibitory amount of a compound to inhibit angiogenesis. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the angiogenesis inhibitor of Friedlander simultaneously with the chemotherapeutic agents of patent '693. One of ordinary skill in the art would have motivated to do so with a reasonable expectation of success by teachings well known in the art, that the synergistic effects of several anti-tumor compounds is beneficial and highly effective in the treatment of angiogenesis.

Art Unit: 1642

19. Claims 75-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedlander et al. (Science 270:1500-1502, December 1, 1995). Friedlander teaches a method for inhibiting angiogenesis as set forth above. Friedlander does not teach the said method wherein administering comprises intravenous, transdermal, intrasynovial, intramuscular, or oral administration, nor in the specified dosages as written in claims 76-79.

However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the composition in a variety of dosages including those designated in the claims. One of ordinary skill in the art would have motivated to do so with a reasonable expectation of success by teachings well known in the art, that dosages of any pharmaceutical agent must be adjusted and optimized.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703) 306-5880. The examiner can normally be reached on Monday through Friday from 7:00 am to 3:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

Alana M. Harris, Ph.D.  
Patent Examiner, Group 1642  
December 4, 2000

*Sheela Huff*  
SHEELA HUFF  
PRIMARY EXAMINER